CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED AMENDMENTS OF SECTIONS 100070 AND 100090

HEARING DATE: None scheduled.

DEADLINE FOR SUBMISSION OF COMMENT: July 6, 2009

SUBJECT MATTER OF PROPOSED AMENDMENTS: SCRO Committee Review and Special Considerations for CIRM-Funded Derivation

SECTIONS AFFECTED: The proposed amendments apply to Chapter 2 and sections 100070 and 100090 of Title 17 of the California Code of Regulations.

100070 – SCRO REVIEW AND NOTIFICATION:

To facilitate coordination among the SCRO, IRB and IACUC, the regulations give institutions flexibility in achieving the regulatory goals off SCRO review and do not over-specify procedures and policies for SCROs. Amendments are specified below:

Subdivision (c):

Purpose: The amendments states that CIRM-funded research with the aim to derive or create a covered stem cell line from human gametes, embryos or products of SCNT involving a human donor nucleus may not commence without SCRO committee review and approval in writing.

Rationale: The Standards Working Group ("SWG") recommended that basic research involving the reprogramming of somatic cells be subject to SCRO notification. This modification limits full SCRO review to derivations involving the use gametes, embryos or SCNT. This amendment achieves the policy objective of requiring SCRO review and approval of research involving human gametes and embryos.

Subdivision (d):

Purpose: These amendments state that CIRM-funded purely in vitro research utilizing covered stem cell lines or the reprogramming human somatic cells with the aim to derive or create a covered stem cell line may not commence without written notification to the designated SCRO committee. Research may include animal assays to evaluate pluripotency; however, subsequent introduction of derived covered stem cell lines in non-human animals shall be reviewed in accordance with section (e).

Rationale: The SWG recommended that basic research involving the reprogramming of somatic cells be subject to SCRO notification. This modification clarifies that

reprogramming is covered under the notification standard including animal assays for the purpose of determining if a line is pluripotent. Stating that subsequent animal transplantation of an established line must be reviewed under the existing standard provides further clarification. This achieves the policy objective to require SCRO notification (but not full review and approval) of iPS research involving human somatic cells.

Subdivision (f):

Purpose: The subdivision as amended states that CIRM-funded research introducing cells from covered stem cell lines into a live born human may not commence without SCRO committee review and approval in writing.

Rationale: The SWG recommended that transplantation research be subject to full SCRO review. This modification, by deleting the word "stem" before "cells" in the first instance clarifies that all research proposing to transplant cells from a covered cell line must be reviewed.

SECTION 100090: ADDITIONAL REQUIREMENTS FOR CIRM-FUNDED RESEARCH:

This section identifies further requirements with which the SCRO must affirm compliance when CIRM funds are used to derive new human stem cell lines. These requirements are in addition to those required by Section 100080, subdivision (e). The amendments are discussed below:

Subdivision (a)(1):

Purpose: As amended, the subdivision states, in pertinent part, that where CIRM funds are to be used for research intended to derive a covered stem cell line from human gametes, embryos, somatic cells or tissue, the SCRO committee must determine the requirements of Code of California Regulations, title 17, section 100080, subdivision (a)(2) or (a)(3), have been met with the following exception: (1) For embryos created on or before August 13, 2008, "valuable consideration" does not include payments to gamete donors in excess of "permissible expenses," provided the embryo was originally created for reproductive purposes.

Rationale: The SWG recommended that "general" consent for research be allowed for gametes, embryos and somatic cells procured prior to the promulgation of the MES regulations. This provision identifies the baseline requirements for consent, payment and oversight. The addition of section 100080(a)(3) allows the use of somatic cell that conform to federal regulations to be utilized. The new text of subdivision (a)(1) exempts embryos created from gametes from which the donors were paid from the payment restriction in 100080(a)(2)(A). This achieves the policy goal of allowing embryos created from gametes from which the donors were paid if the embryo was created for reproductive purposes ((VF) and it was created prior to August 2008.

Subdivision (b):

Purpose: This section that where CIRM funds are to be used for research intended to derive a covered stem cell line from gametes or embryos procured from human subjects, after November 22, 2006, the SCRO committee must confirm that donors provided voluntary and informed consent in accordance with Code of California Regulations, title 17, section 100100, subdivision (b).

Rationale: This provision "triggers" the detailed consent requirements for gametes and embryos procured after the CIRM regulations took effect. Excluding somatic cells from this requirement enables the use of somatic cells procured under protocols that deviate from the specific CIRM requirements. This achieves the goal of requiring comprehensive consent for all gametes and embryos procured after the CIRM regulations take effect.

Subdivision (c):

Purpose: This subdivision states that where a covered stem cell line is derived from human somatic cells, procured from human subjects after November 22, 2006, and the CIRM-funded research is designed to develop cells for transplantation into a live born human; the SCRO committee must confirm that donors provided voluntary and informed consent including the requirements of Code of California Regulations, title 17, section 100100, subdivision (b)(1)(E).

Rationale: It is the policy objective of the ICOC to require explicit consent for cell transplantation. Thus, the provision makes clear that explicit consent is required for transplantation of cells to humans.

**********End**********